510(k) SUMMARY

VASCUTEK TEMPORARY LIMB SALAVE SHUNT

Date prepared – 30 January 2007

FEB 15 2007

Common name of the Device:	Clamp, Vascular
Trade name or Proprietary Name:	Vascutek Temporary Limb Salvage Shunt
Classification Name:	Part 870 Cardiovascular Devices. Subpart E – Cardiovascular Surgical Devices. Vascular clamp (21 CFR 870.4450)
Applicant:	Karen Kelso Regulatory Affairs Manager Vascutek Ltd. Newmains Avenue Inchinnan Industrial Estate Renfrewshire, Scotland PA4 9RR, United Kingdom
Device Predicates:	McPherson Enterprises Inc. Smithwick Carotic Shunt (K062474) Boston Scientific Corp. Hemashield Platinum Woven Double Velour TAAA Graft (K052302) Boston Scientific Corp. Hemashield Platinum Woven/Microvelour (K021213)

Device Description:

The Temporary Limb Salvage Shunt is a hybrid of two types of commercially available Vascutek ePTFE vascular grafts, i.e. Rapidax™ (G060186) and MAXIFLO™ (K992832). A summary of both grafts is detailed below.

The Vascutek Rapidax™ graft comprises an internal ePTFE vascular graft and an external ePTFE layer. These are identical to those used in the manufacture of the MAXIFLO™ Wrap grafts (Figure 1a). In the Rapidax™ graft these surfaces sandwich a

self-sealing elastomer membrane. This membrane has been subjected to *in vitro* and *in vivo* evaluation, both in animals and humans, which ensure its suitability for implant. A representative image of this triple layer effect is detailed in Figure 1b.

Vascutek Rapidax™ and MAXIFLO™ Wrap grafts are manufactured from virgin polytetrafluoroethylene (PTFE) resin. As stated above, this PTFE resin is identical to the PTFE used in the manufacture of Vascutek's other approved ePTFE vascular grafts. This material has an extensive history of use in cardiovascular and other medical applications and all PTFE graft materials have therefore been thoroughly tested and characterized with regard to biocompatibility, physical properties and suitability for the intended use.

The differences associated with the Temporary Limb Salvage Shunt are summarized as:

1 The absence of the outer ePTFE layer
2 The addition of a PTFE external support at both ends and middle of the TLSS
3 The addition of measurement markings along the surface of the TLSS

The Temporary Limb Salvage Shunt is an ePTFE vascular prosthesis which has been modified to facilitate its use as a temporary limb salvage shunt. The device includes an elastomer membrane, external support and graduated markings to allow assessment of depth of insertion as shown in Figures 2 and 3. All these elements are included in the current approved range of Vascutek ePTFE vascular grafts.

The externally supported bevelled ends facilitate the placing of the device within the severed artery. The support in the centre of the device is required if a shorter length is needed to enable the trauma surgeon to cut the device to the required length. The self-sealing membrane permits drugs to be administered directly into the lumen without loss of blood. The graduated markings assist the surgeon in placement of the correct length as illustrated in Figure 3. Specifications are detailed in Table 1.

The mechanical properties of the Vascutek Temporary Limb Salvage Shunt are equivalent to product currently in commercial distribution. *In vitro* testing and other comparisons conducted on the Vascutek Temporary Limb Salvage Shunt show it to be equivalent to the current Vascutek ePTFE vascular grafts (K992832) and other devices used in the intended use application (K062474 : K052302 : K021213). Results from biocompatibility, animal and clinical studies, also demonstrate that the Vascutek Temporary Limb Salvage Shunt is biocompatible and non-toxic.

Intended Use:

The intended use of the Temporary Limb Salvage Shunt is:

"*this device is intended to be used as a temporary bypass shunt in limb threatening trauma cases were there has been damage to a major blood vessel*"

Substantial Equivalence:

In conclusion, the Vascutek Temporary Limb Salvage Shunt is substantially equivalent to the quoted devices in commercial distribution. All devices referenced under this current application are intended for use as arterial conduits.

In summary, all testing and associated documentation demonstrates the Vascutek Temporary Limb Salvage Shunt, to be substantially equivalent to other devices in commercial distribution and a summary of this substantial equivalence is provided in Table 2 with comparison to the predicate devices.

Karen Kebo
Signature

30-01-07
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 15 2007

Vascutek Ltd.
c/o Dr. Karen Kelso
Newmains Ave.
Inchinnan Industrial Estate
Renfrewshire, Glasgow, Scotland, UK PA4 9RR

Re: K070323
Trade Name: Temporary Limb Salvage Shunt (TLSS)
Regulation Number: 21 CFR 870.4450
Regulation Name: Clamp, Vascular
Regulatory Class: Class II
Product Code: DXC
Dated: January 30, 2007
Received: February 2, 2007

Dear Dr. Kelso:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

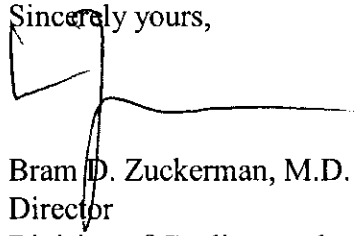
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070323

Device Name: VASCUTEK TEMPORARY LIMB SALVAGE SHUNT

Indications For Use: THIS DEVICE IS INTENDED TO BE USED AS A TEMPORARY BYPASS SHUNT IN LIMB THREATENING TRAUMA CASES WHERE THERE HAS BEEN DAMAGE TO A MAJOR BLOOD VESSEL

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K070323